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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,914	05/30/2002	Lyndell E Kelly	15317	7073

7590

06/25/2003

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EXAMINER

COOK, REBECCA

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/069,914

Applicant(s)

KELLY, LYNDELL E

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-15 is/are rejected.
- 7) ☒ Claim(s) 4,5 and 16 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 4-5, 16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 1-3, 6-7, 10-13 and claim 15 to the extent that it depends on claim 13, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the disclosed doses of cyanohydroxybutene (CHB) to provide apoptosis of pancreatic acinar cells, does not reasonably provide enablement for any and all doses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The discussions in the examples in the specification disclose that the effect of CHB on the pancreatic acinar cell is dose-related. Furthermore, the effect of CHB on liver necrosis is also dose-dependent.

Claims 1-3, 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 6, 7 and 13 the term cyanohydroxybutene is confusing and the specification does not clarify this. Is the intent to claim 1-cyano-2-hydroxy-3-butene or another a compound in which the hydroxy and butene are at different sites in the molecule?

Dependent claims should begin with the word "The" and not "A" to make their dependent status clear.

In claims 1 and 13 it is not clear as to whether the method is in vivo or in vitro, since a subject is not recited. Amending the claim 1 to recite "A method ofin a patient in need thereof..." and claim 13 to recite "A method ofin a subject in need thereof" will overcome this rejection.

There is no antecedent basis in claim 1 for the recitations in claim 2 "said therapeutic window" and "said patient." There is no antecedent basis in claim 13, for the recitation in claim 13, line 4, "said subject."

In claims 5, 6, 7, 10 and 13 the word "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

The term "substantially" in claims 1, 6, 7 and 13 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how much apoptosis and non-regeneration of the pancreatic acinar cells occurs, whether it is 51% or 99%.

The language in claim 7 is not clear as to whether the subject or the pancreatic carcinoma is treated. Amending the claim to recite "A method of treating pancreatic carcinoma involving acinar cells in a subject in need thereof" will overcome this rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maher or Bhatia in view of MEDLINE AN 2000050292.

Maher (entire abstract, lines 5, page 168, column 4) teaches that 1-cyano-2-hydroxy-3-butene (CHB) causes apoptosis of pancreatic acinar cells following a single dose given by gavage. The disclosed dosage range includes those recited in the instant dependent claims.

Bhatia (entire abstract, page 477, left column, lines 7-9, figures) teaches that CHB causes apoptosis of pancreatic acinar cells following a single dose given intravenously.

The instant claims differ over the references in reciting subcutaneous or intra-arterial administration of CHB. Other claims recite treating acinar carcinoma.

However, it would be obvious to one of ordinary skill in the art to use subcutaneous administration of CHB to cause apoptosis of pancreatic acinar cells since MEDLINE An 2000050292 (Kelly) discloses (abstract, line 3) subcutaneous administration of CHB.

Furthermore, it would be obvious to one of ordinary skill in the art to use CHB to treat acinar carcinoma since CHB causes apoptosis of acinar cells and this would have the effect of killing acinar carcinoma cells.

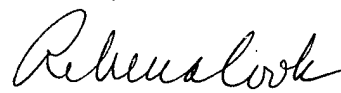
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

June 23, 2003


REBECCA COOK
PRIMARY EXAMINER
GROUP 4200/614